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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/484,886	01/18/2000	Gale E. Smith	674506-2035.2	1236

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EXAMINER
SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
1651	13

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/484,886	SMITH ET AL.	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *June 25, 2003 as Paper Number 12* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *96-124* is/are pending in the application.

4a) Of the above claim(s) *117-124* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *96-116* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

1. Applicants' response to Office Action mailed March 25, 2003 as paper number 11 and amendment filed June 25, 2003 as paper Number 12 is acknowledged and entered. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.

2. Claims 96-124 are pending.

3. Newly submitted claims 117-124 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 117-124 have a totally different scope: any product by the process as opposed to a specific composition, glycosylated erythropoietin, that does not have to be made by the recited process. Furthermore, claims 117-124 are drawn to a method of cell culture and to monitor and control cell culture parameters for said cell culture method.

Since applicants have received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 117-124 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Examiner suggests that the non-elected claims cited *supra* be canceled in response to this Office action to expedite prosecution.

4. Claims 96-116 are examined on merits.

Claim Rejections Under 35 U.S.C. § 102

5. Claims 96-97 and 99-116 stand rejected under 35 U.S.C. §102(b) as anticipated by Quelle et al. (Blood. 1989. Volume 74, Pgs. 652-657) with evidence provided by Dorland's Illustrated Medical Dictionary (W.B. Saunders Co., Philadelphia, 1988, Page 581) for the reasons of record in the Office Action mailed March 25, 2003 as paper number 11.

In response to art rejections under 35 U.S.C.§ 102(b) discussed *supra*, citing a number of Case laws, applicants argue that Quelle et al. with or without Dorlands do not teach or suggest the instantly claimed invention, because the claimed invention is to an in-vivo activity, wherein said activity is an element of the presently claimed invention. Applicants, however, admit on record that Quelle et al's purified recombinant erythropoietin has "little activity in vivo" (See Applicants' response filed June 25, 2003 as paper Number 12, Page 11, lines 29-30).

Applicants' above arguments regarding the rejections to Claims 96-97 and 99-116 have been fully considered but are not persuasive for the reasons of record in Office Action mailed March 25, 2003 as paper number 11. In addition, nowhere in any of the Claims 96-97 and 99-116 applicants have claimed

"in-vivo" activity for said >95% pure, homogeneous recombinant erythropoietin produced by a baculovirus expression system in cultured insect cells. Only place that applicants assert that their recombinant erythropoietin stimulates erythropoisis is in last paragraph of Example 9 (See Page 5, Amendment and response filed December 17, 2002 as Paper Number 10). However, even in that assertion applicants have not demonstrated in-vivo activity of their recombinant erythropoietin. Applicants also assert in above cited paragraph that in contrast to all recombinant erythropoietins reported in prior art literature that applicants cite, applicants' recombinant protein obtained in same way (i.e., expressed in baculovirus vector, wherein said baculovirus is cultivated in insect culture and subsequently said recombinant erythropoietin is purified) as prior literature is different than those from cited literature. However, applicants have not disclosed said distinctness of said erythropoietin vis a vis recombinant erythropoietin/ (s) from said prior art literature (e.g., Quelle et al., Blood. 1989. Volume 74, Pgs. 652-657). Since said distinctiveness is key to the instantly claimed invention, applicants are requested to disclose under 35 U.S.C. § 132, said distinct property including the alleged in-vivo activity of the claimed erythrpoietin vis a vis at least one recombinant erythropoietin (e.g., one that Quelle et al. have reported, since that erythropoietin is closest to the applicants' claimed erythropoietin). In absence of requested comparative data, the examiner-cited prior art deems to anticipate the instantly claimed invention.

Claim Rejections Under 35 U.S.C. § 103(a)

6. Claims 96-116 stand rejected under 35 U.S.C. §103(a) as obvious over Quelle et al. (Blood. 1989. Volume 74, Pgs. 652-657) with evidence provided by Dorland's Illustrated Medical Dictionary (W.B. Saunders Co., Philadelphia, 1988, Page 581) for the reasons of record in the Office Action mailed March 25, 2003 as paper number 11.

In response to the rejections to Claims 96-116 in Office Action mailed March 25, 2003 as paper number 11, applicants argue that the claimed invention is unobvious over the cited reference, because the cited reference does not disclose, teach, incite or suggest, or provide motivation to arrive at the presently claimed invention. This argument is not deemed to be persuasive because of the reasons of record and discussion presented above.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Since Quelle et al disclose a similar

product prepared in the manner and having same range of purity (i.e., 200,000 U/mg to 500,000 U/mg) as disclosed in the claimed invention, the product would intrinsically function in the same, or essentially the same manner as in the claimed invention. Instantly claimed higher purity of said erythropoietin is deemed merely a matter of judicious selection and routine optimization of a result-effective parameter, which is well within the purview of the skilled artisan. Therefore, the product disclosed in the prior at reference would intrinsically stimulate erythropoisis even with "little in vivo activity".

CONCLUSION

7. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. No Claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Daylight Saving, or Standard time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 872-9306.

Kailash C. Srivastava, Ph.D.
Patent Examiner
Art Unit 1651
(703) 605-1196

September 23, 2003

Jon P. Weber, Ph.D.
Primary Examiner